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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/512,009

05/13/2005

Bill Clark

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GE HEALTHCARE, INC.
IP DEPARTMENT
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EXAMINER

RIDER, LANCE W

ART UNIT

PAPER NUMBER

4131

MAIL DATE

DELIVERY MODE

04/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/512,009	Applicant(s) CLARK ET AL.	
	Examiner LANCE RIDER	Art Unit 4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/19/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Amersham PLC, et al.

Claims 1-3 and 10-12 are drawn to a method for analyzing samples collected from a human individual comprising the active steps of hyperpolarizing the enriched or non-enriched NMR active nuclei of a biological sample or biofluid containing one or more test compound(s). Amersham PLC, et al. discloses a method for investigating the fate of a test compound comprising the steps of hyperpolarizing the enriched or non-enriched NMR active nuclei of a biological sample or biofluid containing one or more test compound(s) as outlined in the specification on page 4 paragraphs 3 and 7, and in claims 1-8. All of the active steps for the methods in claims 1-3 and 10-12 are anticipated by Amersham PLC, et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-9 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amersham PLC, et al. as applied to claims 1-3 and 10-12 cited supra, and further in view of et al Streetman, D.S., et al.

Claim 4-9 are drawn to a method for phenotyping human individuals by analyzing biological samples such as urine or blood for the activity of proteins or isozymes on test compounds and then grouping and classifying those individuals.

Streetman, D.S., et al. discloses a phenotyping procedure using (LC/MS/MS) to study the metabolism of the small molecule midazolam in multiple test subjects. Mass spectrometry is a well known technique complimentary to NMR in the art for analyzing small molecules and their metabolic breakdown products as disclosed in Komoroski, E.M., et al. who use both NMR and GC-MS to track the metabolism of drug compounds.

Claims 4-9 are rejected in light of Streetman, D.S., et al. as Streetman discloses a method on page 1 in the abstract for determining the activity of the p450 CYP3A. Claim 5-8 is also rejected in light of Streetman, as Streetman discloses on page 350 paragraphs 6 and 7, page 351 paragraphs 1 and 2, and in Figure 2, a series of experimental methods for determining the phenotypes of patients. Streetman shows a method in which several individuals are characterized for the ability to metabolize midazolam as claimed in claim 5, these individuals are grouped as in claim 6, and this clinical trial group was phenotyped multiple times as in claim 7, these individuals were compared to one another by thorough statistical analysis as in claim 8 and as the

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individuals were phenotyped 8 times as stated in Streetman on page 351 paragraph 3 line 1 they were obviously phenotyped at least once before a second administration of the drug midazolam as claimed in claim 9.

Claims 13-16 are drawn to analyzing a sample from a human individual in which the sample contains a compound which is the substrate, inducer, or inhibitor of an enzyme, in particular a p450. Claims 13-16 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Amersham PLC, et al. as applied to claims 1-3 and 10-12 cited supra, and further in view of et al Streetman, D.S., et al.

Streetman discloses a method for determining the activity of the p450 CYP3A which includes both isoforms CYP3A4 and CYP3A5 upon the probe compound midazolam which is a substrate for CYP3A as disclosed on page 349 paragraph 1 and in the abstract. Claims 13-16 are thus rejected in light of Streetman et al. as all necessary aspects of these are disclosed in the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LANCE RIDER whose telephone number is (571)270-1337. The examiner can normally be reached on Monday through Friday, 7:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624**

**/LANCE RIDER/
Patent Examiner, Art Unit 4131**